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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,710	07/03/2001	Albert Chin	1001.1468101	2449

28075 7590 02/06/2004  
CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

EASHOO, MARK

ART UNIT PAPER NUMBER

1732

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,710

Applicant(s)

CHIN ET AL.

Examiner

Mark Eashoo, Ph.D.

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-27 is/are pending in the application.
- 4a) Of the above claim(s) 16-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 5-7,9,14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restriction*

This application contains claims 16-27 drawn to an invention which were nonelected with written traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 8, and 10 are rejected under 35 USC 102(b) as being anticipated by Kurth et al. (US Pat. 4,790,970).

Regarding claim 1: Kurth et al. teaches the claimed process for forming an extrudate, comprising: providing an extruder having an extrusion head/die (Fig. 13, element 4); extruding an elongate polymeric member (Fig. 13, element 1); solidifying the polymeric member downstream of the extrusion head while the member is at a temperature between its melting temperature and glass transition temperature (4:20-26, 6:60-65 and 7:12-23); and rotating/twisting the polymeric member downstream of the die, in a sizing tool, while at a temperature between its melting temperature and glass transition temperature thereby imparting a helical molecular orientation (2:4-9, 3:29-40, and Fig. 13).

Since the polymeric member of Kurth et al. is still in a thermoplastic condition while in the sizing tool it is inherent that the material is at a temperature between its melting temperature and glass transition temperature. Furthermore, Kurth et al. teaches that the extrudate immediately enters the sizing/orienting tool after exiting the die (6:50-55), therefore, there is no substantial cooling which would allow the polymer temperature to drop below the glass transition before orientation.

Regarding claim 2: Since the polymeric member of Kurth et al. is still in a thermoplastic condition while in the sizing tool it is inherent that the material is at a temperature between its melting temperature and glass transition temperature (4:20-26). Kurth et al. also teaches that the extrudate "immediately enters" the sizing/orienting tool after exiting the die (6:50-55), therefore, there is no heating

Art Unit: 1732

of the polymer temperature between the die and the sizing tool. The phrase "immediately enters" is understood as being readable upon 'close proximity'.

Regarding claims 8 and 10: Kurth et al. teaches forming additional polymeric layers or coatings during the same extrusion process (7:57-66). A person of ordinary skill in the art would recognize that "during the same extrusion process" would clearly suggest continuous co-extrusion.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-13 are rejected under 35 USC 103(a) as being unpatentable over Kurth et al. (US Pat. 4,790,970) in view of Donald (US Pat. 3,404,203).

Regarding claims 11-13: Kurth et al. teaches the basic claimed process as set forth above (see rejection of claim 1).

Kurth et al. does not teach a rotating core member. However, Donald teaches a rotating core member or mandrel (Fig. 1, element 18). Kurth et al. and Donald are combinable because they are from the same field of endeavor, namely, forming hollow tubular structures. At the time of invention a person of ordinary skill in the art would have found it obvious to have used a rotating core member, as taught by Donald, in the process of Kurth et al., and would have been motivated to do so in order to provide internal support during sizing/shaping and addition molecular orientation to the tube material which provide increased strength to the tube.

Since the core member or mandrel of Donald does not extend past the sizing/orientation unit, it is intrinsic that the mandrel is removed from the polymeric tube.

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### ***Allowable Subject Matter***

Claims 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Art Unit: 1732

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach the instant extrusion process as a whole comprising extruding at 10 fpm or more and rotating the extrudate downstream of a die at 1,000 rpm or more.

It is noted that extrusion rates of 10 fpm are generally well known in the extrusion art. However, such extrusion rate in combination with the instant rate of rotation is not. For example, Donald only teaches a rotation rate of about 10 rpm. Although a person of ordinary skill in the art may be able to use or contemplate high rates of rotation, the evidence of record does not provide motivation to do so.

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach the instant extrusion process as a whole comprising intermittent co-extrusion and imparting helical orientation to the extrudate downstream of the extrusion die/head.

It is noted that intermittent co-extrusion is well known in the process of making catheters in order to form various regions of soft and stiff along the length of the catheter. Furthermore, imparting helical orientation to the extrudate is also well known in the extrusion art, as evidenced by van Muiden or Donald, however, this is normally preformed with a rotating die.

Claims 14-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach the instant extrusion process as a whole comprising extruding a second layer over a first extruded core member and imparting helical orientation as claimed.

Art Unit: 1732

***Response to Arguments***

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 886-217-9197 (toll-free).



Mark Eashoo, Ph.D.  
Primary Examiner  
Art Unit 1732

2/21/04

2/2/04  
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